REMARKS

Claims 61-68 were examined and rejected. Claims 1-60 and 69-78 have been previously withdrawn from consideration.

Applicants cancel claims 1-60 and 69-78. Applicants amend claims 61 and submit that no new matter is added therein. This amendment is supported at least by Figures 31, 82, 85 and 87-89 and corresponding text of the Application as filed, without limitation thereto. Applicants submit additional claims 79-83 for consideration and submit that no new matter is added therein. Claims 79 and 80 are supported at least by paragraphs [0004], [0009]-[0010], [0205], [0441]-[0445]; Figures 56 and 82 and texts corresponding to Figures 56 and 82, without limitation thereto. Claim 81 is supported at least by claim 62 and the support noted above for claims 79 and 80, without limitation thereto. Claims 82 and 83 are supported at least by Figure 85 text corresponding to Figure 85, without limitation thereto.

Applicants respectfully request reconsideration of claims 61-68 as amended and reconsideration of claims 70-83 in view of the following remarks.

Information Disclosure Statement

Applicants note with appreciation the Patent Office's identification of shortcomings of the Information Disclosure Statement filed November 2, 2004.

Claim Rejections - 35 U.S.C. §102

Claims 61-63 and 68 are rejected under 35 U.S.C. §102(b) as being anticipated by Sweezer (US 2001/0041864) ("Sweezer"). It is axiomatic that to be anticipated every limitation of the claim must be disclosed in a single reference.

Applicants respectfully disagree with the rejection above for at least the reason that the cited reference does not disclose inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest; and perfusing a blood and/or a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61.

Sweezer discloses arterial output 28 positioned along the length of shaft 22 proximally of occlusion member 24, so that bypass system 27 can pumping blood through output 28 proximal to occlusion member 24 (See Figure 1 and paragraph [0030], line 23). Sweezer also discloses distal opening 30 of shaft 22 for providing cardioplegic fluid from a cardioplegic fluid source 31 external to the vasculature, to the ascending aorta distally of occlusion member 24 (see Figure 1 and paragraph [0031]). Finally, Sweezer discloses suction source 33 external to the vasculature for aspirating blood or other fluid from the ascending aorta through opening 30, such as to maintain a blood-free field (see Figure 1 and paragraph [0031]).

However, the Patent Office has not identified and Applicants are unable to identify any disclosure in Sweezer of inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest; and perfusing a blood and/or treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by amended claim 61. Thus, Applicants respectfully request that the Patent Office withdraw the rejection of claim 61.

Moreover, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 62 for at least the reason of Sweezer does not disclose perfusing a blood and/or treatment agent via a proximal hole through the exterior surface of the cannula at a location proximal to the balloon, and a distal hole through the exterior surface of the cannula from a location distal to the balloon, as required by claim 62. As noted above for claim 61, Sweezer either teaches pumping blood using bypass system 27, through output 28 proximal to occlusion member 24; providing cardioplegic fluid from source 31 external to the vasculature, to opening 30 distal to the occlusion member 24; and/or aspirating blood or other fluid from distal opening 30 to suction source 33 external to the vasculature. However, the Patent Office has not identified and Applicants are unable to identify any disclosure in Sweezer of the above noted limitations of claim 62. Hence, Applicants respectfully request the Patent Office withdraw the rejection of claim 62 for this additional reason.

Claim Rejections - 35 U.S.C. §103

Claims 64-66 are rejected under 35 U.S.C. §103(a) as being unpatentable over Sweezer in view of Sahota (US 5370617) ("Sahota"). Claim 67 is rejected under 35 U.S.C. §103(a) as being unpatentable over Sweezer in view of Alt (US 6805860) ("Alt"). For a claim to be obvious, each limitation of the claim must be taught or suggested by at least one properly combined reference. Furthermore, the combination of elements must be "more than a predictable use of prior art elements according to their established functions." (See KSR International Company v. Teleflex Inc., No. 04-1350 (Supreme Court, April 30, 2007)).

Applicants respectfully disagree with the rejection above for at least the reason that the cited references do not cure the deficiencies of Sweezer noted above for claim 61, from which claim 64-66 depend.

For example, Sahota teaches dilatation catheters for use in administering treatments to relieve stenotic regions within a body lumen while maintaining blood flow past the dilatation balloons (See Abstract). Moreover, Sahota teaches both a perfusing lumen 15 and a guidewire lumen 17, to maintain a steady flow of blood; and having ports 55 and 57 that communicate blood between the two lumens. (see Figure 4; and col. 2 Lines 14-40). Specifically, Sahota teaches maintaining a steady flow of blood using blood channels through both a perfusing lumen 15 and a guidewire lumen 17. (see col. 3 Lines 17-37).

However, the Patent Office has not identified and Applicants are unable to identify any teaching in Sahota of inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest; and perfusing a blood and/or a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61. In other words, the combination of Sahota and Sweezer does not teach the above noted limitations since the perfusion of Sahota can not be stopped to occlude the vessel. (see ports 54 and 56 of perfusing lumen 15 in Figure 4). On the other hand, according to claim 61, for example and without limitation thereto, a blood vessel can be occluded, treated, perfused,

occluded, treated, perfused, etc. without removing the canula and without deflating the occlusion balloon.

Moreover, the combination of Sahota and Sweezer is improper. It can be appreciated that the **primary purpose of Sahota** is to avoid occlusion or reduction of blood flow by maximizing the flow of blood past the expanded balloon (see col. 1 Lines 52-63). Thus, Sahota teaches against occluding as claimed, and can not be properly combined with a reference to teach such a practice. Applicants also note that the **primary purpose of Sweezer** is to infuse cardioplegic fluid 31 into the ascending aorta distal of occlusion member 24 to stop the heart during surgery; aspirate blood and other fluids from the ascending aorta using suction source 32 to vent the heart and aorta to maintain a blood-free field; and then pump blood using bypass system 27, through output 28 proximal to occlusion member 24 to provide cardiopulmonary bypass. It can be appreciated perfusion between the blood proximal to occlusion member 24 (e.g., where outputs 28 are pumping at least 4 Liters/minute) and the ascending aorta distal of occlusion member 24 would destroy any blood-free field in the heart and aorta. Thus, Sweezer teaches against perfusing as claimed, and can not be properly combined with a reference to teach such a practice.

Next, the cited motivation "to provide a method which advantageously uses already present element within the device to better perform and control the medical procedure" is unfounded. As noted above, neither procedure can be combined with, or benefits from adding the other. Moreover, the Patent Office has not identified any advantage, or increase in performance or control, that such a combination would accomplish. Thus, such combination appears to be gleaned only from the claims.

Similarly, Alt fails to cure the deficiencies of Sweezer and Sahota noted above for claim 61. Alt teaches injection of progenitor cells (see col. 13 lines 27-31). However, the Patent Office has not identified and Applicants are unable to identify any teaching in Alt of the above noted limitations, as required by claim 61.

Dependent Claims

Any dependent claims not mentioned here and are asserted as patentable over the cited references for at least the reasons explained herein for allowing their base claims, in addition to any additional limitations of those dependent claims.

Additional Claims 79-83

Additional claims 79-83 are submitted as being patentable at least for the reasons noted above for claim 61 from which they depend.

In addition, regarding claims 79 and 80, Applicants note that **Sweezer's primary purpose** is cardiopulmonary bypass by infusing cardioplegic fluid 31 into the ascending aorta distal of occlusion member 24 to stop the heart during surgery. Thus, aspirating blood and other fluids from the ascending aorta using suction source 32 for venting the heart and aorta to maintain a blood-free field, teaches against perfusing blood and/or treatment agent in a blood vessel coupled by human vasculature to a beating heart as required by claim 79. Also, aspirating blood and other fluids from the ascending aorta using suction source 32 for venting the heart and aorta to maintain a blood-free field teaches against perfusing blood and/or treatment agent in a blood vessel of a person having a beating heart as required by claim 80. Hence, Applicants respectfully request claims 79 and 80 be allowed for these additional reasons.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION
I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Nedy Calderon 10/25/07
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